

Clinical Laboratory Program99 Chauncy Street, 2nd Floor, Boston, MA 02111

(617) 753-8439/8438 (617) 753-8240 - Fax

CLINICAL LABORATORY LICENSE APPLICATION FORM

In Accordance with the "Rules and Regulations Relating to the Operation, Approval and Licensing of Clinical Laboratories" (105 CMR 180.000) the undersigned hereby applies for a license to establish and/or maintain a clinical laboratory at the premises set forth below under the provisions of the General Laws, Chapter 111D.

1. CLINICAL LABORATORY

NAME: _____

ADDRESS: _____
Street City/Town Zip

TELEPHONE: _____

2. APPLICANT/LICENSEE (Proprietor, Corporation, Partnership, or Group)

NAME: _____

ADDRESS: _____
Street City/Town Zip

TELEPHONE: _____

3. TYPE OF OWNERSHIP (** Include a copy of the approved Articles of Incorporation or Partnership AND complete Section I or II, as appropriate, on page 3).☐ Sole Proprietor *** ☐ Partnership *** ☐ Corporation Date Incorporated: _____☐ Other (Specify) _____**4. TYPE OF LABORATORY**☐ Independent ☐ Physician Office # of Physicians: _____☐ Other (Specify) _____**5. TYPE OF LICENSE APPLYING FOR OR RENEWING:**A. ☐ **Full** (High complexity testing) ☐ **Limited** (Moderate complexity testing)B. ☐ **Original** check one of the following: _____☐ New Laboratory: Projected opening date: _____☐ Transfer of Ownership: From: _____ Date of Transfer: _____☐ **Renewal**

Are you applying for a licensure type that is different from the license you currently have (i.e. from a limited license to a full license or vice versa) ?

☐ No ☐ Yes (specify) _____**6. CLIA CERTIFICATE:****Type of certificate that the Laboratory has or has applied for:**☐ Certificate of Waiver ☐ Certificate for Provider Performed Microscopy Procedures☐ Certificate of Accreditation: Accrediting agency: ☐ CAP ☐ COLA ☐ JCAHO ☐ Other: _____☐ Certificate (Regular)

CLIA NUMBER: _____

7. **CLINICAL LABORATORY DIRECTOR:** _____

Name of Contact Person if different from director: _____

8. **SPECIALTIES / SUBSPECIALTIES**

Check each specialty and subspecialty in which tests are performed:

☐ MICROBIOLOGY–SPECIALTY

☐ Bacteriology

☐ Mycology

☐ Parasitology

☐ Virology

☐ Other Microbiology

☐ IMMUNOLOGY–SPECIALTY

☐ Syphilis

☐ Viral Serology [HIV Testing]

☐ Non-Syphilis

☐ CLINICAL CHEMISTRY–SPECIALTY

☐ Routine Chemistry

☐ Endocrinology

☐ Toxicology

☐ Urinalysis

☐ Other Chemistry

☐ IMMUNOHEMATOLOGY–SPECIALTY

☐ Blood Group / Rh Type

☐ Rh Titers

☐ Other Immunohematology [Antibody Work-ups]

☐ HEMATOLOGY–SPECIALTY

☐ Routine Hematology

☐ Cellular Studies

☐ Coagulation

☐ Other Hematology

☐ PATHOLOGY–SPECIALTY

☐ Diagnostic Cytology

☐ Histopathology

☐ Oral Pathology

☐ RADIO BIOASSAY (in-vivo)–SPECIALTY

☐ CYTOGENETICS–SPECIALTY

☐ HISTOCOMPATIBILITY TESTING–SPECIALTY

9. **HOURS OF OPERATION:**

10. **PROFICIENCY TESTING PROGRAMS:**

List Proficiency Testing Program(s) in which the laboratory is enrolled:

Has the proficiency testing service(s) been authorized to send copies of proficiency testing results to the State Agency (Department of Public Health, Clinical Laboratory Program)? _____

TYPE OF OWNERSHIP - COMPLETE IF OWNERSHIP IS A CORPORATION OR PARTNERSHIP****SECTION I:**

If the **Applicant** under Item 2 is a **CORPORATION** list:

Name and title of officers:

Name and business address of all directors and holders of 5% or more of the corporation's stock:

****SECTION II**

If the **Applicant** under Item 2 is a **PARTNERSHIP** list:

Name and business address of all general and limited partners with 5% or greater ownership in the partnership.

** CORI forms must be completed on all of the persons listed in Sections I and II. Refer to fact sheet regarding who else must complete CORI forms.

Attach an additional sheet if necessary.

11. COLLECTION STATIONS:

List contact name, address and telephone number of all collection stations maintained under the license (refer to 180.017 for definition). Attach an additional sheet if necessary.

<u>Contact Name</u>	<u>Address</u>	<u>Telephone number</u>	<u>Days & Hours of Operation</u>

12. SATELLITE LABORATORIES:

List contact name, address and telephone number of all PHYSICIAN OFFICE satellite laboratories maintained under the license (refer to 180.042 for definition). Attach an additional sheet if necessary.

<u>Contact Name</u>	<u>Address</u>	<u>Telephone number</u>	<u>Days & Hours of Operation</u>

APPLICATION FEE

Full License: remit a fee of **\$300 for each Specialty area checked** payable to the **COMMONWEALTH OF MASSACHUSETTS**.

Limited License: remit a fee of **\$300** payable to the **COMMONWEALTH OF MASSACHUSETTS**.

NOTE: IF YOU ARE UNSURE ABOUT WHICH CATEGORY CERTAIN TESTS FALL UNDER PLEASE CONTACT THIS OFFICE FOR CLARIFICATION PRIOR TO SUBMITTING THE APPLICATION OR PAYMENTS.

TAX CERTIFICATION STATEMENT AND SIGNATURE

*(A) Pursuant to M.G.L.c.62C,S.49A I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all State Tax returns and paid all State taxes required by law.

**Social Security Number or Federal Identification Number (voluntary)

(B) I, the undersigned, attest that I am duly authorized to complete and sign this application, that I have read this application in its entirety and that the information contained therein is accurate. I understand that additional information may be required by the Massachusetts Department of Public Health to complete the application process and agree to provide such information as requested. I understand that an unannounced on-site inspection may be made to confirm the information contained herein. Signed under the pains and penalties of perjury on

Date

Signature of Authorized Representative

Title

* A license will not be issued unless this certification clause is signed by the applicant.

** Your Social Security Number/Federal Identification Number will be furnished to the Massachusetts Department of Revenue to determine whether you have met tax filing or payment obligations. Licensees who fail to correct their non-filing delinquency will be subject to license suspension or revocation. This request is made under the authority of Massachusetts General Law c.62Cs.49A.